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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	<i>Application No.</i> 09/700,732	<i>Applicant(s)</i> Whitcombe
	<i>Examiner</i> Arun Chakrabarti	<i>Art Unit</i> 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 1/18/01, 1/19/01, 3/19/01, 4/3/01, 9/4/01, 10/11/01, and 1/31/02.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. 09/700,732.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other:

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DETAILED ACTION

Specification

1. Applicant's election with traverse of Group I, corresponding to claims 1-20, in paper NO: 8 is acknowledged. Applicant's argument for traversal has been considered but is not persuasive because of the following reasons.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT international search report discloses an anticipatory reference (Graham et al. (PCT publication Number: WO 9705280), 13 February, 1997) against claim 1 and therefore, claims of Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Applicant argues that the above mentioned reference is not a proper 102 (b) art. This argument is not persuasive. As a matter of fact, claim 1 has been rejected under 35 U.S.C. 102 (b) in the current office action as described below in detail. Naturally, claims 1-27 does not share a common technical feature. The lack of unity requirement is still deemed proper and ***therefore made Final.***

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-14 recite the limitation "A" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding claims 2, and 4, the phrase "capable of" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Regarding claim 9, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claims 7 and 14 are rejected over the recitation of the phrases, "more than 1-20 TBS", and "greater than 2-100 fold excess over the TBS" respectively. In absence of any upper limit of TBS molecules and fold excess, it is not clear if the infinite number of TBS molecules and fold excess are claimed or not. The metes and bounds of the claims are vague and indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6, 8-13, and 15-20 are rejected under 35 U.S.C. 102 (b) as being anticipated by Graham et al. (PCT International Publication Number WO 97/05280) (February 13, 1997).

Graham et al teach a method for determining the presence or absence of a target nucleic acid sequence in a sample nucleic acid (Abstract), the method comprising :

(a) exposing the sample to a detection agent comprising a metal surface associated with a SER(R)S active species (SAS) and with a target binding species (TBS) (Abstract, Claim 1, and page 16, The SER(R)S-active label Section to page 18, line 8),

(b) observing the sample/agent mixture using SER(R)s to detect any surface enhancement of the label, characterized in that the binding of the TBS to the target sequence causes increased surface enhancement of the SAS (Claim 1 and Figures 3-20).

Graham et al inherently teach a method, wherein the metal surface is not itself capable of surface enhancement when present in the detection agent of step (a) (page 23, The SER(R)S-active surface section, first paragraph).

Graham et al teach a method, wherein the detection agent is exposed to the sample in step (a) as two or more separate components (Abstract, Claim 1, and page 16, The SER(R)S-active label Section to page 18, line 8).

Graham et al teach a method, wherein the detection agent comprises a first agent and a second agent each having a different TBS, each TBS being capable of binding to the target sequence, and wherein the binding of the first and second TBS to the target sequence brings a

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metal surface associated with each TBS into proximity thereby causing surface enhancement of an SAS associated one or both of the metal surfaces (Table 1 and page 31, modification of the target or target binding species Section to page 35, third paragraph and page 26, last paragraph to page 27, second paragraph);

Graham et al teach a method, wherein the detection agent comprises monodisperse unaggregated colloidal metal particles associated with a TBS comprising a nucleic acid or nucleic acid analog which is complementary to all or part of the target sequence (Table 1, page 16, The SER(R)S-active label Section to page 18, line 8, page 24, second paragraph, and page 31, modification of the target or target binding species Section to page 35, third paragraph).

Graham et al teach a method, wherein the TBS comprises peptide nucleic acid (Page 35, third paragraph and page 39, last paragraph to page 40, line 4).

Graham et al inherently teach a method, wherein there are more than one TBS per metal colloid particle (Claim 2 and Table 1);

Graham et al teach a method, wherein a surface seeking group (SSG) is used to promote chemi-sorption of the SAS and /or TBS to the metal surface (page 40, chemi-sorptive functional group on the label subsection to page 44, line 5).

Graham et al teach a method, wherein the SSG is benzotriazole and azobenzotriazole and is modified with a dye which is SAS (Claims 16-19 and page 40, chemi-sorptive functional group on the label subsection to page 44, line 5).

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Graham et al teach a method, wherein more than one target sequence is determined using multiple detection agents having distinguishable SAS (Page 61, last paragraph to page 62, first paragraph);

Graham et al teach a method, wherein

Graham et al teach a method, wherein the modified SSG is used to associate the TBS to the metal surface (page 40, chemi-sorptive functional group on the label subsection to page 44, line 5).

Graham et al teach a method, wherein the modified SSG is conjugated to the TBS via a linker group (Page 28, introduction of polyamine Section to page 34, third paragraph).

Graham et al inherently teach a method, wherein the target sequences share sequence identity, and wherein a common first agent is used in conjunction with specific distinguishable second agents which can discriminate between the remainder of the target sequences (Abstract, and page 16, The SER(R)S-active label Section to page 18, line 8).

Graham et al teach a method for detecting the presence of, or selecting, or identifying, or phylogenetically classifying, an organism, the method comprising use of a method wherein the target nucleic acid sequence is associated with that organism (Uses of the Invention Section, page 59, last paragraph to page 64, second paragraph).

Graham et al teach a method for diagnosing a disease, the method comprising use of a method wherein the target nucleic acid sequence is associated with that disease (Uses of the Invention Section, page 60, last paragraph).

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Graham et al teach a method for isolating a nucleic acid encoding a specific gene, the method comprising use of a method wherein the target sequence corresponds to a sequence associated with, or within, that gene (Uses of the Invention Section, page 59, last paragraph to page 64, second paragraph).

Graham et al teach a process for producing a detection agent, the process comprising the step of combining unaggregated metal particles with a SAS and a TBS, whereby the SAS and TBS associate with the metal particles via an SSG (Page 28, introduction of polyamine Section to page 34, third paragraph and page 40, chemi-sorptive functional group on the label subsection to page 44, line 5).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-20 are rejected under 35 U.S.C. 103 (a) over Graham et al. (PCT International Publication Number WO 97/05280) (February 13, 1997).

Graham et al teach the method of claims 1-6, 8-13, and 15-20 as described above.

Graham et al do not teach the method, wherein there are more than 1-20 TBS per metal colloidal particle and wherein the SAS is present in greater than 2-100 fold excess over the TBS.

However, it is *prima facie* obvious that selection of the specific number of TBS per metal colloidal particle and specific concentration ratio of SAS over the TBS represents routine optimization with regard to production of desired binding complex and quantity as well as quality of nucleic acid analyte, which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the specific number of TBS per metal colloidal particle and specific concentration ratio of SAS over the TBS selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

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Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun kr. Chakrabarti
Arun Chakrabarti,

Patent Examiner

February 12, 2002